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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,472	12/14/2001	Christopher Kern	02481.1767	1068

7590 02/18/2004

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Washington, DC 20005-3315

EXAMINER
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LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/014,472

Applicant(s)

KERN ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8 and 11-18 is/are pending in the application.  
4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 3-8 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in Paper No. 6 dated December 19, 2002 is acknowledged.
2. Claim 9-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6 dated December 19, 2002. The restriction requirement was made final in Paper No. 7, dated March 26, 2003.
3. Newly submitted claims 11-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly added claims 11-18 are drawn to a method of reducing the activity of a matrix metalloproteinase which is different from a method of treating or preventing a disorder as reducing the activity of a matrix metalloproteinase would not necessarily result in treating or preventing of the disorder.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Applicant's Response dated June 26, 2003***

4. In the Response filed June 26, 2003, claims 2, 9, and 10 were canceled; claims 1 and 3 were amended; and claims 11-18 were added. Applicant presented arguments directed to the rejection of claims 1-8 under 35 U.S.C. 112, first paragraph; the rejection of claims 1-8 under 35 U.S.C. 112, second paragraph; and the rejection of claims 1-8 under 35 U.S.C. 103(a). Claims 1, 3-8, and 11-18 are pending. Claims 11-18 are drawn to a nonelected invention. An action on the merits of claims 1 and 3-8 is contained herein below.

5. The rejection of claims 1 and 3-8 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the Office Action dated March 26, 2003.

6. The rejection of claims 1 and 3-8 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record as set forth in the Office Action dated March 26, 2003.

7. Applicant's arguments with respect to claims 1 and 3-8 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

***Objections/Rejections of Record Set For the in Office Action dated March 26, 2003***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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9. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of certain matrix metalloproteinases, does not reasonably provide enablement for treating the wide breadth of disorders conceivably embraced by the claims, and in particular, does not reasonably provide enablement for preventing any disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1 and 3-8 have been amended to provide specific disorders to be treated or prevented by the instantly claimed method; however, the specification does not provide enablement for preventing said disorders. Applicant argues that following a successful treatment protocol, it is entirely within the skill of the art to continue administering the same drug in order to “prevent” recurrence. Applicant’s arguments are not persuasive as the claimed method is not limited to “preventing recurrence” of the disorder. The claims are currently constructed to embrace methods wherein “healthy subjects” (subjects with no previous history of the disorders to which the instantly claimed method is drawn) are prevented from ever obtaining said disorder.

10. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “enhanced activity” in claim 1 is a relative term that renders the claim indefinite. The term “enhanced activity” is not defined by the claim, the specification

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does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

No arguments have been set forth by applicant.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 and 3-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeda Research and Development WO 92/19249 (Yeda).

Yeda discloses the administration of low molecular weight heparin (LMWH) compositions for the prevention and/or treatment of pathological process involving the induction of TNF- $\alpha$  secretion (page 7, lines 9-30; page 8, lines 1-6; page 11, lines 27-34). LMWH disclosed by Yeda includes enoxapirin in doses of 20 mg / 0.2 ml and 40 mg / 0.4 ml of water. The compositions are administered in any manner as dictated by the particular application at hand including, but not limited to, enteral administration (including oral) or parenteral administration (including topical or inhalation with the aid of aerosols). In preferred embodiments, the compositions are administered subcutaneously or intravenously.

**Conclusion**

13. Claims 1, 3-8, and 11-18 are pending. Claims 11-18 are drawn to a nonelected invention. Claims 1 and 3-8 are rejected. No claims are allowed.

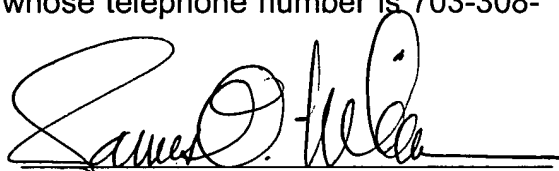
**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD  
Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

ptl  
February 14, 2004